

2009-1270
(Serial No. 09/719,045)

United States Court of Appeals
for the
Federal Circuit

IN RE: ANDREW P. CHAPMAN and DAVID J. KING

*Appeal from the United States Patent and Trademark Office,
Board of Patent Appeals and Interferences*

**REPLY BRIEF OF APPELLANTS
ANDREW P. CHAPMAN AND DAVID J. KING**

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AUGUST 24, 2009

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party)

Appellants Chapman and King certify the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Andrew Paul Chapman and David John King

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

UCB Pharma S.A.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

UCB Pharma S.A. is wholly-owned by UCB S.A.

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4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Woodcock Washburn LLP - Doreen Yatko Trujillo and Ellen M. Klann

Cozen O'Connor P.C. - Doreen Yatko Trujillo

August 24, 2009
Date

Doreen Yatko Trujillo
Signature of counsel

Doreen Yatko Trujillo

Printed name of counsel

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INTRODUCTION

Citing *In re Rijckaert*, the Acting Director of the United States Patent and Trademark Office (“the Director”) states that, once the United States Patent and Trademark Office (“USPTO”) demonstrates a *prima facie* case of obviousness, the burden shifts to applicant to show nonobviousness. (Red Br. at 13, citing *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993).) The Director alleges that Chapman did not carry this burden.

Although Chapman maintains that the USPTO did not make out a *prima facie* case of obviousness (A255; A267-268), as the case cited by the Director makes clear, only the burden of going forward with argument or evidence shifts to the applicants once the USPTO makes out a *prima facie* case, not the ultimate burden of proving nonobviousness. *Rijckaert*, 9 F.3d at 1532. Upon meeting the burden of going forward with argument or evidence, which Chapman clearly did, the USPTO was to determine patentability on the totality of the record, not just Chapman’s rebuttal.

After evidence or argument is submitted by the applicant in response, patentability is determined on the **totality** of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992, emphasis added). Chapman contends that when the totality of the record is properly considered, Chapman has

established the nonobviousness of claims 1-10 and 12-15 by a preponderance of the evidence.

I. The Board's Factual Errors Regarding The Scope And Content Of The Prior Art Were Not Harmless

The Director stops short of admitting that the Board made factual errors regarding the scope and content of the prior art. Instead, the Director argues that any errors were harmless because none of the statements cited by Chapman form the basis of the Board's obviousness rejection (Red Br. at 13). The Director's assertions regarding harmlessness, however, are contrived.

Although the Board's discussion of obviousness spans almost five pages and references Fact Findings 2, 4-9 and 11-13 (A7-A11), the Director asserts that the Board set forth its obviousness rejection on only pages A9-10 of its decision and based the rejection on a single Fact Finding – Fact Finding 8 (Red Br. at 13-15).¹ The Director's assertions limiting the basis for the Board's decision conveniently allow the Director to dismiss all of Chapman's arguments pertaining to the factual errors regarding the scope and content of the prior art as "red herrings" because Chapman's arguments pertaining to these factual errors refer to pages of the Board's decision other than pages A9 and A10 and/or to Fact Findings other than Fact Finding 8 (Red. Br. at 13-15). Chapman is not aware of any precedent

¹ Chapman is particularly puzzled by the assertion attempting to limit the basis to Fact Finding 8 because Fact Findings 2-9 and 13 are cited on pages A9-10 of the Board's decision (A9-10).

supporting the Director's assertions limiting the basis for the Board's decision to certain pages of its decision, much less to a single fact finding; nor did the Director cite any.

Regardless, when the individual errors themselves are analyzed, they are clearly harmful. The first error noted by Chapman is the observation by the Board that the examiner found that Gonzalez teaches a dumbbell-shaped antibody structure of two monovalent Fab' fragments (Blue Br. at 20; A8). In the Decision on Appeal, the Board concluded that "a likely path a person of ordinary skill would take in making a dumbbell-shaped antibody structure would have been to link the disclosed Fab' fragments at the cysteine residues using the bifunctional linker" (A10). This error clearly affected the Board's decision and was, thus, harmful. *In re Watts*, 354 F.3d 1362, 1369 (Fed. Cir. 2004).

The Director tried to dismiss this error by referring to Fact Finding 8, stating that this fact finding does not restrict the dumbbell-shaped structure to Fab' fragments (Red Br. at 14). The Director's assertion, however, disregards what the Board stated in its Decision on Request for Rehearing. In the Decision on Request for Rehearing, the Board specifically referred to their prior statement that the examiner found Gonzalez teaches a dumbbell-shaped antibody structure of two monovalent Fab' fragments, and stated that their "characterization of the Examiner's argument would have been understood to include Gonzalez's explicit

description, as well as what it would have reasonably suggested to persons of ordinary skill in the art" (A22).

The second error noted by Chapman regards the examiner's Fact Finding 7 (Blue Br. at 21; A5-6). In Fact Finding 7, the examiner alleges that Gonzalez describes conjugates containing an $F(ab')_2$ antibody in which the polymer is attached **between** the disulphide bridge that would ordinarily link the heavy and light chains (A5). On page 8 (A9) of its decision, citing Fact Finding 7, the Board states that Gonzalez describes $F(ab')_2$ antibodies in which the polymer is linked **between** light and heavy chains, with only one cysteine residue between them (A9). This error clearly affected the Board's decision and was, thus, harmful. *In re Watts*, 354 F.3d at 1369.

The third error noted by Chapman regards the Board's statement in the Decision on Request for Rehearing that Chapman's assertion that the Board acknowledged that different types of antibody fragments could be used was incorrect (Blue Br. at 22; A23). Chapman cited Fact Finding 3 in the Request for Rehearing as the basis for its statement (A336). Fact Finding 3 lists several species of antibody fragments other than Fab' (A5).² In the Decision on Request for

² The Director incorrectly states that Chapman argues that the Board erroneously found that Gonzalez limits the antibody fragments in Fact Finding 3 (Red Br. at 15). Chapman's argument was, rather, that despite Fact Finding 3, the Board alleged that Chapman's assertion that different types of antibody fragments could be used in the dumbbell-shaped structure was incorrect (Blue Br. at 22).

Rehearing, the Board argued that Fact Finding 3 did not refer to the dumbbell-shaped structure (A23). As stated above, in the Decision on Appeal, the Board concluded that “a likely path a person of ordinary skill would take in making a dumbbell-shaped antibody structure would have been to link the disclosed Fab’ fragments at the cysteine residues using the bifunctional linker” (A10). The Board’s conclusion was clearly based upon an inappropriately narrow interpretation of Gonzalez as evidenced by its refusal to acknowledge that different fragments could be used. This error clearly affected the Board’s decision and was, thus, harmful. *In re Watts*, 354 F.3d at 1369.

II. Gonzalez Teaches Away From Chapman’s Invention

The Director argues that Chapman’s assertions regarding multiple functional groups suggesting multiple attachment locations on the antibody fragments is incorrect (Red Br. At 16). The Director, however, misstates Chapman’s argument. Chapman’s argument was not that a single antibody fragment would be attached to the polymer at multiple points but, rather, that multiple types of attachments would be used to attach the antibody fragments to the polymer (Blue Br. At 23-24). Chapman maintains that the use of multiple types of attachments teaches away from Chapman’s invention.

The Director asserts that Chapmans’ argument that the discussion in Gonzalez to avoid disulphide bridges when attaching polymers to divalent

antibody fragment teaches away takes the Gonzalez disclosure out of context because the cited discussion is directed to a linkage between a heavy and light chain, not two heavy chains (Red Br. At 17-18). Chapman did not take Gonzalez out of context. Chapman noted that Gonzalez was referring to the bridge between the heavy and light chain (Blue Br. at 24). Chapman maintains, however, that Gonzalez teaches away from having the polymer serve as a non-disulphide bridge in a divalent antibody fragment such as claimed by Chapman (Blue Br. at 24). Indeed, the Board cited the disclosure of Gonzalez teaching the elimination of one of two cysteine residues when placing the polymer between the heavy and light chains of an $F(ab')_2$ in its reversal of the anticipation rejection (A14).

III. The Board Employed Impermissible Hindsight

In its brief, the Director argues that Gonzales addresses and solves the very same problem as Chapman in the very same way – by site-specific attachment of polymers to antibody fragments (Red Br. at 18). If Gonzalez solves the same problem as Chapman, however, it is difficult to comprehend how there can be motivation to make Chapman's invention based upon Gonzalez. Consistent with this, Gonzalez reports that the conjugates described substantially improved circulation half-life, mean residence time, and clearance rate as compared to the underivatized parental antibody fragments (A411, abstract).

With no problem to solve, some other basis for rendering Chapman's invention must be shown. Under *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007), an invention can be rendered obvious if it is "obvious to try" as long as certain other conditions are met. As the Director stated, however, the Board did not apply an "obvious to try" standard (Red Br. at 20).³

As Chapman asserted previously, the Board's allegations in reversing the anticipation rejection support Chapman's contention that one of skill in the art would only arrive at Chapman's invention using Chapman's disclosure as a guide (Blue Br. at 27-28). In reversing the anticipation rejection, the Board noted the variety of linkages available for crosslinking the polymer to the antibody; observed that the dumbbell-shaped structure is open to interpretation as to where the coupling is to occur; cited the disclosure of Gonzalez teaching the elimination of one of two cysteine residues when placing the polymer between heavy and light chains of an F(ab')₂; and expressly disagreed with the examiner's assertion that, when Fab'-SH is utilized to form the dumbbell shape, persons skilled in the art would necessarily arrive at the claimed structure (Blue Br. at 27-28, citing A13-A14). Indeed, the Board observed that,

while the sulfhydryl linkage is preferred in the context of a single Fab' fragment, there is the need for picking and choosing among the various possible crosslinking sites to produce a divalent antibody

³ Chapman maintains that, considering the variables, the invention is not obvious under an obvious to try standard.

comprised of two Fab' fragments which are linked via a polymer at a hinge cysteine.

(A13, emphasis added.)

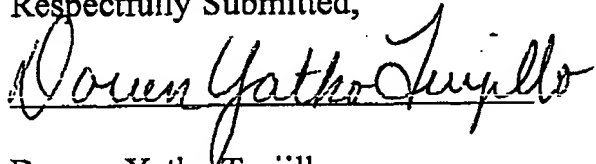
The Director tried to explain the apparent inconsistency in the Board's reasoning by stating that, while Gonzalez did not disclose a specific molecule falling within the scope of Chapman's claim 1, it leads a skilled artisan directly to Chapman's claimed invention, rendering it obvious (Red Br. at 20). But, considering all the variables listed above, Gonzalez clearly cannot lead the skilled artisan **directly** to Chapman's claimed invention. One would have to use hindsight reconstruction to pick and choose among Gonzalez' isolated disclosures. This is inappropriate. *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988). ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention.")

CONCLUSION

Chapman respectfully request this Court to reverse the Board's decision of May 27, 2008 finding Chapman's claimed invention obvious over Gonzalez and obvious over Gonzalez in view of Barbanti.

Dated: August 24, 2009

Respectfully Submitted,

A handwritten signature in cursive script, reading "Doreen Yatko Trujillo", written over a horizontal line.

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CERTIFICATE OF SERVICE

**United States Court of Appeals
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No. 2009-1270

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I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

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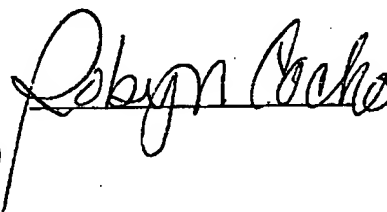
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August 24, 2009

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B), because it contains 1,830 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).

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Dated: August 24, 2009

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